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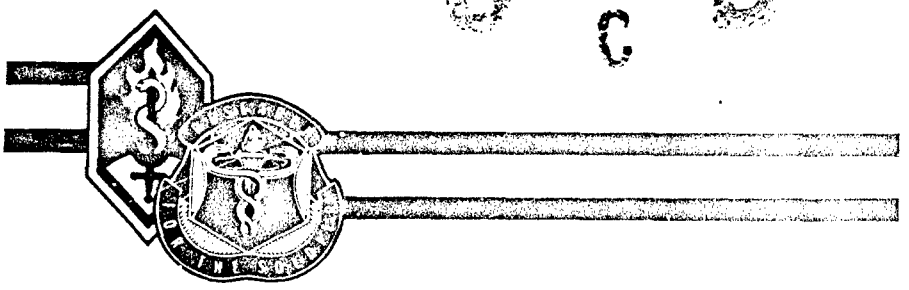

Test and Evaluation Report of the Physio Control Blood Pressure Monitor Model LIFESTAT® 100

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The Physio Control Blood Pressure Monitor Model LIFESTAT® 100 was tested for electromagnetic interference/compatibility in the UH-60A helicopter under the U.S. Army Program for Testing and Evaluation of Equipment for Aeromedical Operations. The tests were conducted using current military and industrial standards and procedures for electromagnetic interference/compatibility and human factors. The LIFESTAT® 100 was found to be compatible with U.S. Army medical evacuation UH-60A Blackhawk.

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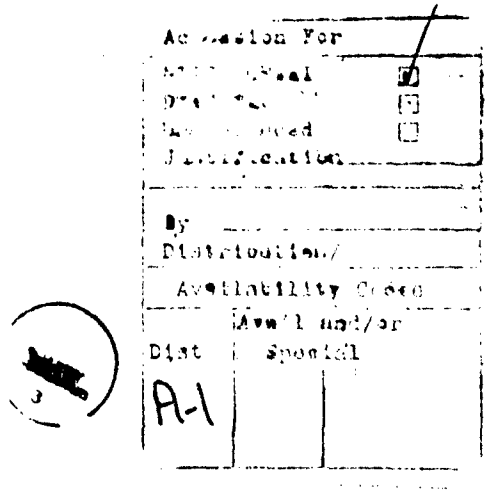

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Section 1. Executive digest

The Army program for Test and Evaluation of Aeromedical Equipment uses existing military standards (MIL-STD) and collective professional expertise to test and evaluate selected medical equipment proposed for use aboard Army aircraft. Equipment meeting these standards ensures the safety of the crew, patients, and aircraft by eliminating risks due to: (1) Interference by the medical equipment with aircraft systems/subsystems operation, (2) the aircraft system's interference with the operation of the medical equipment, (3) the medical equipment's susceptibility to environmental exposure, or (4) physical and/or functional incompatibility while in use on board selected rotary-wing aircraft. This program tests both developmental and nondevelopmental (off the shelf) medical equipment destined for use aboard Army medical evacuation aircraft.

1.1 TEST OBJECTIVES

1.1.1 To determine if the medical equipment is complete and operational per the manufacturer's operating instructions.

1.1.2 To ensure the electrical safety of the medical equipment.

1.1.3 To ensure the equipment will function as designed throughout the rated battery operation time.

1.1.4 To ensure the safety of the operator, the patient, and the aircrew.

1.1.5 To assess design considerations which, potentially, could contribute to an operator error.

1.1.6 To determine if the medical equipment can function as designed in a low-pressure environment.

1.1.7 To determine the ability of the medical equipment to withstand the vibrational stresses expected in a rotary-wing flight environment without degradation or malfunction.

1.1.8 To determine the ability of the medical equipment to be stored and operated in a high-temperature environment.

1.1.9 To determine the ability of the medical equipment to be stored and operated in a low-temperature environment.

1.1.10 To determine the ability of the medical equipment to operate satisfactorily for short periods during exposure to highly humid conditions.

1.1.11 To assess the levels of electromagnetic emissions produced by the medical equipment within selected frequency ranges.

1.1.12 To assess the minimum electromagnetic susceptibility levels of the medical equipment within selected frequency ranges.

1.1.13 To assess the physical and/or functional compatibility of the medical equipment while in use on board the aircraft.

1.1.14 To assess the electromagnetic interference (EMI) and electromagnetic compatibility (EMC) characteristics of the medical equipment with the host aircraft and its installed systems.

1.2 TESTING AUTHORITY

Research and Technology Work Unit Summary, dated 5 October 1989. Project number 3M463807D836, titled, Army Program for Testing and Evaluation of Equipment for Aeromedical Operations.

1.3 SCOPE

1.3.1 This test was conducted at the United States Army Aeromedical Research Laboratory (USAARL), Cairns Army Airfield (CAAF), and designated test flight areas in and around Fort Rucker, Alabama.

1.3.2 The USAARL UH-60A aircraft, serial number 88-26069, with subsystems delineated in paragraph 3.2.2, was configured with the Physio Control blood pressure monitor, model LIFESTAT® 100* and used as the test aircraft for the in-flight evaluation. The in-flight evaluation required 6.5 flight hours.

1.3.3 Laboratory testing was accomplished at USAARL using government furnished equipment (GFE) by Universal Energy Systems (UES), Inc., under contract No. DAMD 17-86-C-6215.

1.3.4 Prior to flight testing, the following tests were accomplished: Acceptance inspection, equipment training, electromagnetic compatibility, human factors and safety, environmental compatibility, and in-flight compatibility.

1.3.5 An airworthiness release (AWR) dated August 1990 was received from the U.S. Army Aviation Systems Command (AVSCOM) prior to the in-flight testing of the Physio Control LIFESTAT® 100.

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* See list of manufacturers

1.4 MATERIAL DESCRIPTION

The Physio Control LIFESTAT® 100 is a portable blood pressure and pulse measurement device. It is used for noninvasive determination of systolic, diastolic, and mean arterial pressures, and pulse rate. The operation is controlled by a microprocessor-based system. The systolic and diastolic pressures and pulse rates are presented on separate light emitting diode (LED) digital displays; mean arterial blood pressure is displayed by pushing a "RECALL/MAP" button. The instrument is powered by either internal battery or ac line power. The battery is a rechargeable, sealed lead-acid type. The front panel of the instrument contains the LED displays, five membrane switch controls, the power switch, a Luer fitting for connecting the blood pressure cuff, and a handle for carrying the unit.

1.5 SUMMARY

1.5.1 Laboratory testing

1.5.1.1 Battery life evaluation: The LIFESTAT® 100 was set to take automatic measurements at 5-minute intervals after the internal battery was fully charged. It operated in this mode for 5.5 hours with internal battery power. This value exceeds the operator manual specification of 2 hours operation in this mode.

1.5.1.2 Electrical safety evaluation: All measurements were within acceptable limits. No unsafe qualities were found in the LIFESTAT® 100. The limits for currents and resistances were in accordance with (IAW) the National Association of Fire Prevention (NAFP) standards.

1.5.1.3 Human factors evaluation: The LIFESTAT® 100 was found to be satisfactory in all major categories of the evaluation criteria with one exception. There are no externally accessible fuses, circuit breakers, or calibration points. The "T" adaptor, which is used during calibration checks, must be supplied by the user.

1.5.1.4 Environmental tests: The LIFESTAT® 100 can be expected to perform in a variety of environmental conditions. Its performance was found to be satisfactory in all stages of the environmental testing. The requirements for environmental tests are established in MIL-STD-810D, methods 500.2 (altitude), 514.3 (vibration), 501.2 (high temperature), 502.2 (low temperature), and 507.2 (humidity).

1.5.1.5 Radiated emissions tests (RE02): The LIFESTAT® 100 may be unsatisfactory for use in certain EMI sensitive environments. Narrowband (NB) and broadband (BB) radiated emissions were detected in the test frequency ranges. Some narrowband and

broadband emissions exceeded the test limits. Emission limits are set forth in MIL-STD-461A, Notice 4.

1.5.1.6 Radiated susceptibility test (RS03): The LIFESTAT® 100 was found to be susceptible to radio frequency interference at 30 MHz. The field strength required to produce errors was 4.22 V/m with a vertically polarized radiator and 10 V/m with a horizontally polarized radiator. At this frequency (30 MHz), all segments of the LED displays illuminated instantly and simultaneously.

1.5.1.7 Conducted emissions test (CE01, CE02, and CE04): Narrowband signals were detected in the frequency range 1.7 to 41.7 MHz, with magnitudes 0.4 to 13.5 dB over specification limits. Broadband emissions were detected in the frequency range 1.8 to 26.7 MHz, with magnitudes 0.5 to 12.9 dB over specification limits.

1.5.1.8 Conducted susceptibility test (CS02 and CS06): Noise generated on the power lines by the LIFESTAT® 100 was greater than the test signal level. No susceptibility to the test power line spikes was noted in the LifeStat® 100.

1.5.2 In-flight testing

1.5.2.1 During the in-flight human factors evaluation, the LIFESTAT® 100 was found to be satisfactory in all categories of the evaluation criteria with one exception. There are no externally accessible fuses, circuit breakers, or calibration points.

1.5.2.2 The aircraft and its subsystems were not adversely affected by the operation of the LIFESTAT® 100 in any of the prescribed flight test modes.

1.5.2.3 The LIFESTAT® 100 was not affected by the aircraft and its subsystems during the in-flight testing.

1.6 CONCLUSIONS

Based on the results of laboratory and in-flight testing, the LIFESTAT® 100 was found to be compatible with U.S. Army medical evacuation UH-60A Blackhawk with the subsystems listed in paragraph 3.2.2.

Section 2. Subtests

2.1 INITIAL INSPECTION

2.1.1 Objective

To determine if the LIFESTAT® 100 is complete and operational for testing per the manufacturer's operating instructions.

2.1.2 Criteria

2.1.2.1 The physical inventory is conducted solely for investigation and documentation.

2.1.2.2 The LIFESTAT® 100 will display consistent and accurate measurements as an acceptable performance test.

2.1.3 Test procedure

2.1.3.1 A complete physical inventory of the LIFESTAT® 100 was completed per the manufacturer's equipment list.

2.1.3.2 An operational validation test of the LIFESTAT® 100 was conducted per the manufacturer's operating instructions by USAARL's medical maintenance personnel.

2.1.4 Test findings

2.1.4.1 The LIFESTAT® 100 was inventoried and found to be complete.

2.1.4.2 The LIFESTAT® 100 operated as prescribed in the manufacturer's operating manual P/N 802609-01. Criteria met.

2.2 BATTERY LIFE EVALUATION (Laboratory)

2.2.1 Objective

To ensure the equipment will function as designed throughout the rated battery operation time.

2.2.2 Criterion

Verify manufacturer's specified full power internal battery life expectancy of 2 hours during continuous operation in the 5-minute cycle mode, in which blood pressure measurements are taken automatically at 5-minute intervals.

2.2.3 Test procedure

2.2.3.1 Charging and operation cycles were conducted in ambient room conditions.

2.2.3.2 The LIFESTAT® 100 was operated continuously using its fully charged internal battery in the 5-minute cycle mode until a low battery indication occurred. The depletion time was noted and the battery was recharged. This procedure was repeated three times.

2.2.4 Test findings

The test was conducted using the fully charged internal battery. The average operating time in testing was 5.5 hours at room temperature. This exceeds manufacturer's specification of 2 hours. Criterion met.

2.3 ELECTRICAL SAFETY EVALUATION

2.3.1 Objective

To ensure the electrical safety, by evaluation of case-to-ground resistance and case-to-ground current leakage, of the LIFESTAT® 100.

2.3.2 Criterion

The LIFESTAT® 100 shall meet the standards established in NAFP 99 for electrical safety of medical equipment.

2.3.3 Test procedure

Measurements in the electrical safety evaluation were made with a Neurodyne-Dempsey model 431F electrical safety analyzer*, IAW the procedures described in Technical Bulletin (TB) Number 38-750-2. Case-to-ground resistance and various case-to-ground leakage currents were measured. Leakage currents were measured using a 10 by 20 centimeter aluminum foil sheet taped flush to the equipment case. Checks were made for safety concerns such as case integrity, breaks in power cord insulation, and connectors.

2.3.4 Test findings

Grounding conductor resistance was 78.7 milliohms and maximum case leakage current was 27 microamperes. These measurements are below the limits specified in NAFP 99. Criterion met.

2.4 HUMAN FACTORS EVALUATION (Laboratory)

2.4.1 Objectives

2.4.1.1 To assure the safety of the operator, the potential patient, and the aircrew.

2.4.1.2 To assess the design considerations which, potentially, could contribute to an operator error.

2.4.2 Criterion

The LIFESTAT® 100 must be rated satisfactory in all major categories of the evaluation. These include visual displays, controls, maintainability, conductors, fasteners, test points, test equipment, fuses and circuit breakers, labels and coding and safety.

2.4.3 Test procedure

2.4.3.1 The evaluation was conducted in a laboratory under fluorescent lighting and ambient room conditions.

2.4.3.2 The LIFESTAT® 100 was operated according to prescribed instructions through its full range of functions.

2.4.4 Test finding

The LIFESTAT® 100 was found to be satisfactory in all of the evaluation criteria with one exception. There are no externally accessible fuses, circuit breakers or calibration points. Criterion partially met.

2.5 ALTITUDE (LOW PRESSURE) TEST [IAW MIL-STD-810D, METHOD 500.2]

2.5.1 Objective

To determine if the LIFESTAT® 100 can function as designed in a low-pressure environment.

2.5.2 Criterion

The LIFESTAT® 100 will display consistent and accurate measurements while exposed to an altitude equivalency of 15,000 feet above sea level.

2.5.3 Test procedure

2.5.3.1 A pretest performance check was conducted to ensure proper operation of the LIFESTAT® 100.

2.5.3.2 The altitude test was performed in a Tenney Engineering model 64S altitude chamber*. This test is based on MIL-STD-810D, Method 500.2. The LIFESTAT® 100 was turned on in the standby mode and placed on the floor of the chamber. Chamber pressure was decreased to 420 mmHg (15,000 ft equivalent altitude) over a 15-minute period, held constant for 60 minutes, then raised, at 1500 fpm, to ambient conditions (760 mmHg) over a 10-minute period. There are no provisions for the control of temperature or humidity inside this chamber.

2.5.3.3 A posttest performance check was conducted to ensure proper operation of the LIFESTAT® 100 after the exposure to low pressure.

2.5.4 Test findings

2.5.4.1 The pretest performance check met criterion 2.1.2.2.

2.5.4.2 No failures in the performance of the LIFESTAT® 100 were noted before, during, or after the altitude test. Criterion met.

2.5.4.3 The posttest performance check met criterion 2.1.2.2.

2.6 VIBRATION TEST [IAW MIL-STD-810D, METHOD 514.3]

2.6.1 Objective

To determine the ability of the LIFESTAT® 100 to withstand the vibrational stresses expected in a rotary-wing environment without degradation or malfunction.

2.6.2 Criterion

The LIFESTAT® 100 will remain operational and be able to display consistent and accurate measurements while exposed to vibrational stresses.

2.6.3 Test procedure

2.6.3.1 A pretest performance check was conducted to ensure proper operation of the LIFESTAT® 100.

2.6.3.2 The vibration test was performed using an Unholtz-Dickey model TA115-40/CSTA vibration test system*. It is a single-axis system with an electromagnetic driver unit. The test consisted of sinusoidal vibrations superimposed on random vibrations over a frequency range of 500 Hz, as shown below. These vibrations are derived from measurements taken on the floor under the copilot's seat in a UH-1 helicopter traveling at 120 knots. The reference spectrum breakpoints are from MIL-STD-810D, Method 514.3; reference spectrum levels are based on field measurements with a

conservatism factor of 1.5. Independent tests were conducted in the X, Y, and Z axes.

Z-axis

duration: 60 minutes
broadband intensity: 0.4506 G_{rms}
random vibration: initial slope : 99.00 dB/Hz
5 Hz level: 0.00006210 $G_{sqr/Hz}$
100 Hz level: 0.0006210 $G_{sqr/Hz}$
300 Hz level: 0.0006210 $G_{sqr/Hz}$
500 Hz level: 0.00006210 $G_{sqr/Hz}$
final slope: -99.00 dB/oct
sinusoidal vibration: .5450 G_{pk} at 11.25 Hz
.1690 G_{pk} at 22.50 Hz
.1200 G_{pk} at 33.75 Hz
.0310 G_{pk} at 45.00 Hz
.0530 G_{pk} at 56.25 Hz

X and Y axes

duration: 60 minutes each
broadband intensity: 0.3099 G_{rms}
random vibration: initial slope: 99.00 dB/oct
5 Hz level: 0.00002920 $G_{sqr/Hz}$
100 Hz level: 0.0002920 $G_{sqr/Hz}$
300 Hz level: 0.0002920 $G_{sqr/Hz}$
500 Hz level: 0.00002920 $G_{sqr/Hz}$
final slope: -99.00 dB/oct
sinusoidal vibration: .3200 G_{pk} at 11.25 Hz
.0670 G_{pk} at 22.50 Hz
.0950 G_{pk} at 33.75 Hz
.0350 G_{pk} at 45.00 Hz
.0770 G_{pk} at 56.25 Hz

The LIFESTAT® 100 was strapped to the vibration table fixture, and its performance was evaluated before, during, and after exposure to vibration.

2.6.3.3 A posttest performance check was conducted to ensure proper operation of the LIFESTAT® 100.

2.6.4 Test findings

2.6.4.1 The pretest performance check met criterion 2.1.2.2.

2.6.4.2 No failures in the performance of the LIFESTAT® 100 occurred before, during, or after exposure to vibration. Criterion met.

2.6.4.3 The posttest performance check met criterion 2.1.2.2.

2.7 HIGH TEMPERATURE TEST [IAW MIL-STD-810D, METHOD 501.2]

2.7.1 Objective

To determine the ability of the LIFESTAT® 100 to be stored and operated in a high-temperature environment.

2.7.2 Criteria

2.7.2.1 The LIFESTAT® 100 will display consistent and accurate measurements during the high-temperature operation check.

2.7.2.2 The LIFESTAT® 100 will display consistent and accurate measurements after the high-temperature storage cycle.

2.7.3 Test procedure

2.7.3.1 A pretest performance check was conducted to ensure proper operation of the LIFESTAT® 100.

2.7.3.2 The high-temperature test was conducted in a Tenney Engineering model ZWUL-10107D walk-in controlled environment chamber*. This test is based on MIL-STD-810D, Method 501.2. For the high-temperature operation test, the LIFESTAT® 100 was turned on in the standby mode and placed on the floor of the environmental chamber. The chamber temperature was raised to 49°C and the humidity was stabilized at a maximum of 20 percent RH within 15 minutes. The environmental control system is capable of regulating temperature within ± 2°C and humidity within ± 5 percent RH. Temperature and humidity were held constant for 2 hours. At 30-minute intervals, the chamber door was opened briefly to minimize the change in chamber conditions during performance checks. After the operational test, the LIFESTAT® 100 was allowed to return to ambient conditions over a 30-minute period.

2.7.3.3 A posttest performance check was conducted to ensure proper operation of the LIFESTAT® 100.

2.7.3.4 The LIFESTAT® 100 was stored (not operated) at temperatures of 63°C for 1 hour, 71°C for 4 hours, then again at 63°C for 1 hour. The chamber and LIFESTAT® 100 then were returned to ambient conditions over a 30-minute period.

2.7.3.5 A poststorage performance check was conducted to ensure proper performance of the LIFESTAT® 100.

2.7.4 Test findings

2.7.4.1 The pretest performance check met criterion 2.1.2.2.

2.7.4.2 No operational failures occurred during the high-temperature test. Criterion met.

2.7.4.3 The posttest performance check met criterion 2.1.2.2.

2.7.4.4 The LIFESTAT® 100 functioned properly after the high-temperature storage test. Criterion met.

2.8 LOW TEMPERATURE TEST [IAW MIL-STD-810D, METHOD 502.2]

2.8.1 Objective

To determine the ability of the LIFESTAT® 100 to be stored and operated in a low-temperature environment.

2.8.2 Criteria

2.8.2.1 The LIFESTAT® 100 will display consistent and accurate measurements during the low-temperature operation check.

2.8.2.2 The LIFESTAT® 100 will display consistent and accurate measurements after the low-temperature storage cycle.

2.8.3 Test procedure

2.8.3.1 A pretest performance check was conducted to ensure proper operation of the LIFESTAT® 100.

2.8.3.2 The LIFESTAT® 100 was placed on the floor of the environmental chamber and the temperature was lowered to 0°C within 25 minutes. The environmental control system is capable of regulating temperature within 2°C. Humidity cannot be controlled in the chamber at freezing temperatures. The temperature was held constant for 2 hours. The chamber door was opened briefly every 30 minutes to minimize the change in chamber conditions, and a performance check was conducted. The chamber temperature then was raised to ambient temperature within a 30-minute period.

2.8.3.3 A posttest performance check was conducted to ensure proper operation of the LIFESTAT® 100.

2.8.3.4 The LIFESTAT® 100 was "stored" in a nonoperational mode. The LIFESTAT® 100 was placed on the floor of the environmental test chamber and the temperature was lowered to -46°C for 6 hours. The chamber then was raised to ambient temperature over a 30-minute period.

2.8.3.5 A poststorage performance check was conducted to ensure proper operation of the LIFESTAT® 100.

2.8.4 Test findings

2.8.4.1 The pretest performance check met criterion 2.1.2.2.

2.8.4.2 No operational failures occurred during the low-temperature test. Criterion met.

2.8.4.3 The posttest performance check met criterion 2.1.2.2.

2.8.4.4 The LIFESTAT® 100 functioned properly after the low-temperature storage test. Criterion met.

2.9 HUMIDITY TEST [IAW MIL-STD-810D, METHOD 507.2]

2.9.1 Objective

To determine the ability of the LIFESTAT® 100 to operate satisfactorily for short periods of time during exposure to highly humid conditions.

2.9.2 Criterion

The LIFESTAT® 100 will display consistent and accurate measurements while exposed to a high-humidity environment.

2.9.3 Test procedure

2.9.3.1 A pretest performance check was conducted to ensure the proper operation of the LIFESTAT® 100.

2.9.3.2 The humidity test was conducted in a Tenney Engineering model ZWUL-10107D walk-in controlled environment chamber*. This test is based on MIL-STD-810D, Method 507.2. For the humidity test, the LIFESTAT® 100 was placed ready for operation on the floor of the environmental chamber. The chamber temperature was raised to a temperature of 30°C and a relative humidity of 95 percent within 25 minutes. Temperature and relative humidity were maintained for 4 hours. The environmental control system is capable of regulating temperature within ± 2°C and humidity within ± 5 percent RH. At 45-minute intervals, the performance of the blood pressure monitor was checked. The chamber door was opened briefly to minimize the change in chamber conditions. The chamber and the LIFESTAT® 100 were returned to ambient conditions before the posttest performance validation check was conducted.

2.9.3.3 A posttest performance check was conducted to ensure the proper operation of the LIFESTAT® 100.

2.9.4 Test findings

2.9.4.1 The pretest performance check met criterion 2.1.2.2.

2.9.4.2 No failures were noted in the LIFESTAT® 100 performance checks conducted during the exposure to the high humidity environment. Criterion met.

2.9.4.3 The posttest performance check met criterion 2.1.2.2.

2.10 ELECTROMAGNETIC CHARACTERISTICS TEST [IAW MIL-STD-461A, Notice 4, and MIL-STD-462, Notice 3]

2.10.1 Objectives

2.10.1.1 To assess the maximum levels of radiated electromagnetic emissions produced by the LIFESTAT® 100 in the 14 kHz to 12.4 GHz frequency range.

2.10.1.2 To assess the tolerances of radiated electromagnetic susceptibility of the LIFESTAT® 100 within the 10 kHz to 10 GHz electric field.

2.10.2 Criteria

2.10.2.1 The LIFESTAT® 100 will not produce emissions in excess of the limits set forth in MIL-STD-461A, Notice 4, paragraph 6.13.

2.10.2.2 The LIFESTAT® 100 will not malfunction when it is subjected to radiated emissions as specified in MIL-STD-461A, Notice 4, paragraph 6.20.

2.10.2.3 The LIFESTAT® 100 shall not conduct emissions in excess of the limits set forth in MIL-STD-461A, Notice 4, paragraphs 6.1 and 6.2.

2.10.2.4 The LIFESTAT® 100 shall not malfunction when it is subjected to conducted emissions as specified in MIL-STD-461A, Notice 4, paragraphs 6.7 and 6.10.

2.10.3 Test procedure

2.10.3.1 The radiated emissions test was performed according to MIL-STD-462, Notice 3, Method RE02. The LIFESTAT® 100 was positioned on a wooden test stand inside the EMI chamber, 1 meter away from the receiving antennas. The antennas were mounted for both vertical and horizontal polarities and connected to EMI receivers. The LIFESTAT® 100 was connected through an extended tube to a cuff outside the chamber. The cuff was placed around a test engineer's arm while the LIFESTAT® 100 took blood pressure

measurements at 2-minute intervals. While the LIFESTAT® 100 was operating, the frequency spectrum (14 kHz to 12.4 GHz) was scanned for emissions. The LIFESTAT® 100 was operated with both ac and battery power.

2.10.3.2 The radiated susceptibility test was performed according to MIL-STD-462, Notice 3, Method RS03. The LIFESTAT® 100 was positioned on a wooden test inside the EMI chamber, 1 meter away from the transmitting antennas. The antennas were mounted for both vertical and horizontal polarities and connected to radio frequency (RF) transmitters. The LIFESTAT® 100 was connected through an extended tube to a cuff outside the chamber. The cuff was placed around a test engineer's arm while the LIFESTAT® 100 took blood pressure measurements at 2-minute intervals. While the LIFESTAT® 100 was operating, it was monitored for faulty operation during exposures to fields of 1 V/m from 10 kHz to 2 MHz, and 5 V/m from 2 to 30 MHz, 10 V/m from 30 MHz to 2 GHz, and 5V/m from 2 to 10 GHz. The LIFESTAT® 100 was operated with ac power only.

2.10.3.3 The conducted emissions tests were performed according to MIL-STD-462, Notice 3, Methods CE02 and CE04. The LIFESTAT® 100 was placed on a grounded, copper covered workbench. The top of the workbench was 1 meter from floor level, 1.37 meters long and 0.81 meters wide. Power was supplied via a pair of line impedance stabilization networks (LISN) and a test jig. The test jig is a wooden tray with two power receptacles and two slots to hold current probes in place around power supply conductors. While the LIFESTAT® 100 was operating, the frequency range (10 kHz to 50 MHz) was scanned for emissions conducted in the power cable from the LIFESTAT® 100.

2.10.3.4 The conducted susceptibility spike test was performed according to MIL-STD-462, Notice 3, Method CS06, on a chemical resistant counter top. Power was supplied via a customized metal connection box. The connection box has two power receptacles and four banana jacks on its front panel. Connections to the individual power lines are made in series through the banana jacks. Transient spikes of 100 volts, 10 microseconds were generated with a Solar Electronics model 8282-1 transient pulse generator* and induced onto the power leads at the connection box banana jacks. The spikes were monitored with a Tektronix 2235 oscilloscope* connected to a power receptacle on the connection box. The LIFESTAT® 100 was plugged into the other receptacle on the connection box and placed in operation. It was observed for correct operation and visual displays while it was subjected to the power line spikes.

2.10.3.5 The conducted susceptibility test was performed according to MIL-STD-462, Notice 3, Method CS02. The LIFESTAT® 100 was placed on a grounded, copper covered workbench. Radio

frequency interference was induced on the power leads and measured at the LIFESTAT® 100 power cable. The frequency of the interference was incremented over the 50 kHz to 400 MHz range while the LIFESTAT® 100 was operated. It was observed for correct operation and visual displays while it was subjected to the radio interference on the power leads. Each frequency was held for 15 seconds.

2.10.4 Test findings

2.10.4.1 During the radiated emissions test, emissions which exceeded specification limits of MIL-STD-461A, Notice 4, were detected in the narrowband frequency range 500 kHz to 317 MHz, with magnitudes 0.2 to 45.7 dB over the specification limits, and in the broadband frequency range 10 to 100 MHz, with magnitudes 0.4 to 33.7 dB over the specification limits. Criterion partially met.

2.10.4.2 The LIFESTAT® 100 was found to be susceptible to radio frequency interference at 30 MHz. The field strength required to produce errors in the LIFESTAT® 100 was 4.22 V/m with a vertically polarized radiator, and 10 V/m with a horizontally polarized radiator. At this frequency (30 MHz) all segments of the LED displays illuminated at once. Criterion partially met.

2.10.4.3 Narrowband signals were detected in the frequency range 1.7 to 41.7 MHz, with magnitudes 0.4 to 13.5 dB over specification limits. Broadband emissions were detected in the frequency range 1.8 to 26.7 MHz, with magnitudes 0.5 to 12.9 dB over specification limits. Criterion partially met.

2.10.4.4 Noise generated on the power lines by the LIFESTAT® 100 was greater than the test signal level. It was not susceptible to radio frequency interference from test spikes during the conducted susceptibility tests. Criterion partially met.

2.11 IN-FLIGHT HUMAN FACTORS EVALUATION

2.11.1 Objective

To assess the physical and/or functional compatibility of the LIFESTAT® 100 while in use on board the aircraft.

2.11.2 Criterion

The flight surgeon will be able to operate the LIFESTAT® 100 without physical or functional restrictions aboard the aircraft. Major areas of concern include: Proper operation, visual displays, controls, maintainability, conductors, fasteners, test points, test equipment, fuses and circuit breakers, labels and coding, and safety.

2.11.3 Test procedure

2.11.3.1 A human factors evaluation was performed IAW MIL-STD-1472D, AAMI human factors guidelines, and UL-544 to ensure the compatibility of the LIFESTAT® 100 and the in-flight environment. The flight surgeon conducted the test wearing a flight suit, flight gloves, and an SPH-4 flight helmet. An evaluation of the compatibility with the nuclear, biological, and chemical (NBC) protective equipment was not conducted. Due to restrictions of the AWR, testing was conducted during daylight hours only.

2.11.3.2 The LIFESTAT® 100 was placed on the floor of the aircraft next to the bottom pan of the litter carousel which was configured for four patients. The litter carousel was flown in the "load" position (perpendicular to the long axis of the helicopter). The LIFESTAT® 100 was tested with the cuff placed on the right arm of a simulated patient laying in the bottom pan of the litter carousel. The LIFESTAT® 100 was tested using both ac and battery power in all flight scenarios required by the In-Flight Test Operations Procedures (ITOP) (refer to section 3.2).

2.11.4 Test findings

During the in-flight human factors evaluation, the LIFESTAT® 100 was found to be satisfactory in all but one of the categories of the evaluation criteria. The only deficiency was the lack of externally accessible fuses, circuit breakers or calibration points and was noted in the laboratory evaluation (paragraph 1.5.1.3). Criterion partially met.

2.12 IN-FLIGHT EMI/EMC CHARACTERISTICS

2.12.1 Objective

To assess the EMI/EMC characteristics of the LIFESTAT® 100 with the host aircraft and its installed systems.

2.12.2 Criteria

2.12.2.1 The LIFESTAT® 100 will not radiate EMI to disrupt or interfere with other equipment or systems aboard the aircraft.

2.12.2.2 The aircraft will not radiate EMI to disrupt or interfere with the LIFESTAT® 100's operation.

2.12.3 Test procedure

A qualitative EMI/EMC assessment was performed with both the LIFESTAT® 100 and the aircraft operating as source and victim. The LIFESTAT® 100 and applicable aircraft instruments and systems

were monitored for unusual operation, readings, surges, or power anomalies for each checklist item (see pages 3-5 through 3-8).

2.12.4 Test findings

2.12.4.1 There were no adverse instances of EMI/EMC noted with the LIFESTAT® 100 acting as either the source or victim. Criterion met.

2.12.4.2 There were no adverse instances of EMI/EMC noted with the aircraft acting as either the source or victim. Criterion met.

Section 3. Supporting documentation

3.1 DETAILED TEST INFORMATION

3.1.1 General information

3.1.1.1 LIFESTAT® 100 testing is not considered a major action significantly affecting the quality of the human environment and, therefore, qualifies for categorical exclusion A-28, Appendix A, AR 200-1.

3.1.1.2 A safety pilot will be designated for each flight. Flight operations will be conducted IAW the aircraft operator's manual, appropriate aircrew training manuals, and test item technical data.

3.1.2 Material description

3.1.2.1 The Physio Control LIFESTAT® 100 is a portable blood pressure and pulse measurement device. It is used for noninvasive determination of systolic, diastolic, mean arterial pressures, and pulse rate. The operation is controlled by a microprocessor-based system. The systolic and diastolic pressures and pulse rates are presented on separate LED digital displays; mean arterial blood pressure is displayed by pushing a "RECALL/MAP" button. The instrument is powered by either internal battery or ac line power. The battery is a rechargeable, sealed-acid type. The front panel of the instrument contains the LED displays, five membrane switch controls, the power switch, a Luer fitting for connecting the blood pressure cuff, and a handle for carrying the unit.

3.1.2.2 Method of operation: The LIFESTAT® 100's operation is based on the oscillometric technique. Arterial pulsations acting against the inflated cuff are used to determine blood pressure and pulse rate. These pulsations are analyzed by an internal computer which determines systolic, diastolic, and mean arterial pressures, and pulse rate. It is able to distinguish between real heart beats and a certain amount of motion artifact. With too much artifact the computer displays "---" rather than incorrect information. Cuff inflation pressure is user variable to 165 mmHg (LO), 220 mmHg (HI), or 50 to 290 mmHg (OVERRIDE) in the manual mode. Cuff inflation pressure is user variable to 165 mmHg (LO), or 220 mmHg (HI) in the automatic mode, with timed measurements at 1, 2, 5, 15, and 30-minute intervals.

3.1.2.3 Dimensions: 7.9 x 11.7 x 3.5 in (20.1 x 29.7 x 8.9 cm).

3.1.2.4 Weight: 8 lb (3.6 kg), not including charger and accessories.

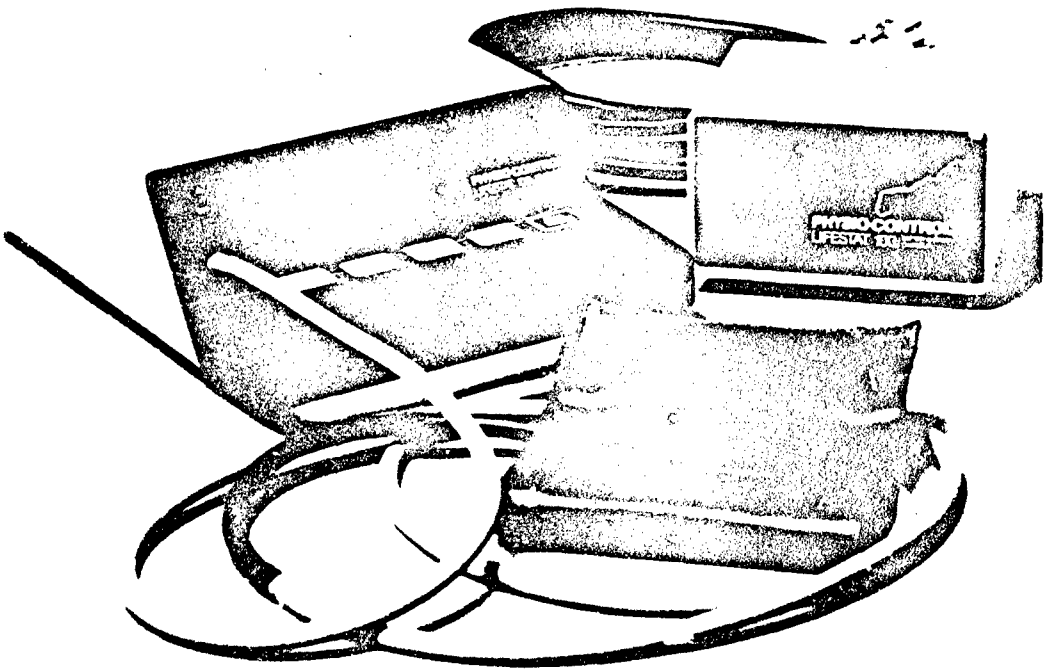
3.1.2.5 Standard accessories: Charger/adapter, pediatric cuff, adult cuff, large adult cuff, thigh cuff, latex extension sets, operating and service manual operating instructions.

3.1.2.6 Power requirements: 120 Vac, 60 Hz, 0.25 amps, 28 watts. Internal battery is a sealed lead-acid type, 9.8 V nominal, 2.5 amp hrs. Battery capacity is approximately 2 hours in the 5-minute cycle mode. Time to fully charge a depleted battery is 16 hours (2 hours to provide 70 percent of full charge capacity).

3.1.2.7 Environmental considerations: Atmospheric pressure, less than 11,000 ft.; operating temperature, 0 to 45 degrees C; storage temperature, -30 to 65 degrees C; relative humidity, 0 to 95 percent.

3.2 TEST DATA

3.2.1 Photographic description



3.2.2 Aircraft equipment list

Item No.	Nomenclature
1	Receiver radio -- R-1496A/ARN-89 (automatic direction finder)
2	Displacement gyro -- CN-1314/A
3	Gyro directional -- CN-998/ASN-43
4	Signal data converter -- CV-3338/ASN-128
5	Receiver -- R-2139/ARN-123 (VOR/LOC/MB/GS)
6	Command instrument system processor -- 70600-01038-101
7	SAS amplifier -- 70901-02908-104 (flight control stability augmentation system)
8	Rate gyro -- TRU-2A/A
9	Amplifier, impedance -- AM-4859A/ARN-89
10	Cargo hook -- FE-7590-145
11	Receiver, radar -- RT-1193/ASN-128 (doppler navigation receiver)
12	Barometric altimeter -- AAU-31/A-1
13	Barometric altimeter -- AAU-32A
14	Receiver/transmitter -- RT-1300/ARC-186 (VHF-AM and/or FM radio)
15	UHF-AM radio set -- RT-1518/ARC-164
16	Interphone control -- C6533/ARC (aircraft intercom control)
17	Receiver/transmitter -- RT-1115D/APN-209 (radar altimeter)
18	Indicator altimeter -- ID-1917C/APN-209 (radar altimeter)
19	Control radio set -- C-7392A/ARN-89 (automatic direction finder)
20	Comparator signal data -- CM-482/ARC-186 (comparator for ARC-186)
21	Receiver/transmitter -- RT-1296A/APX-100 (transponder with IFF)
22	Computer display unit -- CP-1252/ASN-128 (doppler navigation system)
23	Compass set controller -- C-8021E/ASN75
24	Magnetic compass - standby -- MS-17983-4

3.2.3 In-flight test data card

DATA CARD FORMAT

GUIDELINE FOR DATA COLLECTION

IN-FLIGHT SUITABILITY TEST OF MEDICAL ITEMS

1. Installation/removal.	Suitable Yes	Suitable No	Comments
a. Weight and balance (DD Form 365-4, Clearance Form F).	X		
b. Space/area allocation.			
(1) Operational requirements.	X		
(2) Storage requirements.	X		
c. Interface connections (safe, positive, secure).	X		
d. Installation/removal (expedient/easily achieved).	X		
e. Mounting/final configuration (functional/stable).	X		

2. Operations and performance.	Suitable Yes	Suitable No	Comments
a. Manufacturer's operating instruction.	X		
b. Medical item operation before aircraft run-up.	X		
c. System interface during aircraft engine run-up and medical item operation (EMI switchology checklist).	X		
(1) Aircraft voltage output.	X		
(2) Flight control function (UH-60).	X		

	Suitable Yes	Suitable No	Comments
(3) Stabilator function (UH-60).	X		
(4) Radio communication vs medical item operation.			
(a) FM	X		
(b) UHF	X		
(c) VHF	X		
(5) Navigation equipment vs medical item operation.			
(a) Transponder	X		
(b) ADF	X		
(c) VOR	X		
(d) Doppler	X		
(6) Radar altimeter operation vs medical item operation.	X		
d. System interface during aircraft hover and medical item operation (EMI switchology checklist).			
(1) Voltage output.	n/a		
(2) Radio communication vs medical item operation.			
(a) FM	X		
(b) UHF	X		
(c) VHF	X		

	Suitable Yes	No	Comments
(3) Navigation equipment operation vs medical item operation.			
(a) Transponder	X		
(b) ADF	X		
(c) VOR	X		
(d) Doppler	X		
e. Flight mission profile vs medical item operation (EMI switchology checklist).			
(1) Straight and level (1000 ft m.s.l. for 20 minutes).			
(a) Compatibility of flight mode and medical item operation.	X		
(b) Radio communication vs medical item operation.			
a. FM	X		
b. UHF	X		
c. VHF	X		
(2) NOE (20 minutes). compatibility of flight mode and medical item operation.	X		
(3) FM homing (10 minutes).	X		
(4) Doppler navigation vs medical item operation.			
(a) Initialize function.	X		
(b) Fix function.	X		
(c) Update function.	X		

	Suitable Yes	Suitable No	Comments
(5) VOR navigation 7000 ft m.s.l. for 20 minutes) vs medical item operation.	X		
(6) ILS approach vs medical item operation.	X		
f. Medical item operation after engine shutdown (external power source).	X		
g. Restrictions to the medical item's use (i.e., electrical connectors).	X		
h. Deviations from the laboratory test results.			
(1) Electrical/ electronic.		None	
(2) Mechanical environment.		None	
(3) Human factors (user interface, controls, markings, lighting, egress).		None	
(4) Safety.		None	

3. Deviations from the in-flight test protocol.

The VOR navigation portion of the in-flight test conducted at 2000 feet m.s.l. due to air traffic control clearance.

3.2.4 EMI switchology checklist

EMI SWITCHOLOGY CHECKLIST UH-60 AIRCRAFT

IN-FLIGHT SUITABILITY OF MEDICAL ITEMS

ENG INSTRUMENTS/CDU	No EMI Affect	EMI Affected Gnd	EMI Affected Flt	Explanation
Fuel quantity	X			
Fuel indicator test	X			
XMSN oil temperature	X			
XMSN oil pressure	X			
#1 engine oil temperature	X			
#2 engine oil temperature	X			
#1 engine oil pressure	X			
#2 engine oil pressure	X			
#1 TGT	X			
#2 TGT	X			
#1 Ng speed	X			
#2 Ng speed	X			
CDU digits on/off	X			
CDU instruments dim	X			

ENG INSTRUMENTS/PLT PDU	No EMI Affect	EMI Affected Gnd	EMI Affected Flt	Explanation
#1 engine RPM	X			
#2 engine RPM	X			
Rotor RPM	X			
#1 torque	X			
#2 torque	X			

ENG INSTRUMENTS/COPLT PDU	No EMI Affect	EMI Affected Gnd	EMI Affected Flt	Explanation
#1 engine RPM	X			
#2 engine RPM	X			
Rotor RPM	X			
#1 torque	X			
#2 torque	X			

ENG CONTROLS	No EMI Affect	EMI Affected Gnd	EMI Affected Flt	Explanation
#1 overspeed	X			
#2 overspeed	X			
RPM switch	X			
#1 engine anti-ice	X			
#2 engine anti-ice	X			
#1 inlet anti-ice	X			
#2 inlet anti-ice	X			

RADIO EQUIPMENT	No EMI Affect	EMI Affected Gnd	EMI Affected Flt	Explanation
ICS, C-6533 ARC	X			
VHF-FM, ARC-186/115	X			
VHF-AM, ARC-186/115	X			
UHF-AM, ARC-164(V)	X			
Crypto, KY-28	Not installed			
Radio retransmissions PLN	Not installed			
Transponder, APX-100(V)	X			
KIT-1A/TSEC IFF computer	Not keyed with code			

MISSION EQUIPMENT	No EMI Affect	EMI Affected Gnd	EMI Affected Flt	Explanation
RWR, APR-39(V)	Not installed			
IR CM, ALQ-144	Not installed			
Chaff dispenser, M-130	Not installed			
Cargo hook system	X			

HYDRAULIC CONTROL SYSTEM	No EMI Affect	EMI Affected Gnd	EMI Affected Flt	Explanation
Backup hydraulic pump	X			
Servo off 1st stage/PLT	X			
Servo off 2nd stage/PLT	X			
Servo off 1st stage/COPLT	X			
Servo off 2nd stage/COPLT	X			
Hydraulic leak test	X			
Tail servo	X			
Boost servos	X			

FUEL SYSTEM	No EMI Affect	EMI Affected Gnd	EMI Affected Flt	Explanation
Fuel pump switch	X			
Fuel boost pump #1	X			
Fuel boost pump #2	X			
Fuel cont panel ESSS	Not installed			

WARNING SYSTEM	No EMI Affect	EMI Affected Gnd	EMI Affected Flt	Explanation
Low rotor RPM	X			
Master caution	X			
Caution advisory	X			
Fire warning	X			
AFCS	X			
Stabilator	X			
#1 engine out	X			
#2 engine out	X			

NAVIGATION INSTRUMENTS	No EMI Affect	EMI Affected Gnd	EMI Affected Flt	Explanation
ADF	X			
Magnetic compass	X			
CONUS NAV, ARN-123	X			
Doppler, ASN-128	X			
Gyro mag compass (PLT)	X			
Gyro mag compass (COPLT)	X			
Compass cont panel, ASN-75	X			
HSI	X			

FLIGHT INSTRUMENTS	No EMI Affect	EMI Affected Gnd	EMI Affected Flt	Explanation
Radar altimeter	X			
Stabilator pos indicator	X			
VSI	X			
CIS mode select	X			
SAS 1	X			
SAS 2	X			
FPS	X			
Trim	X			
Go-around enable	X			
Cyclic trim release	X			
Cyclic stick trim	X			
ALR encoder	X			

FLIGHT INSTRUMENTS (CONT)	No EMI Affect	EMI Affected Gnd	EMI Affected Flt	Explanation
HSI/VSI mode select (PLT)				
DPLR	X			
VOR/ILS	X			
BACK CRS	X			
FM HOME	X			
TURN RATE	X			
CRS HDG	X			
VERT GYRO	X			
BRG 2	X			
HSI/VSI Mode Select (COPLT)				
DPLR	X			
VOR/ILS	X			
BACK CRS	X			
FM HOME	X			
TURN RATE	X			
CRS HDG	X			
VERT GYRO	X			
BRG 2	X			

MISCELLANEOUS EQUIPMENT	No EMI Affect	EMI Affected Gnd	EMI Affected Flt	Explanation
Blade deice	Not tested			Ambient temperature was out of test limits.
Windshield anti-ice	X			
Pitot heat	X			
Vent blower	X			
Windshield wiper	X			
Heater	X			
APU	X			
Generator #1	X			
Generator #2	X			
Generator APU	X			
Air source heat start	X			
Tail wheel lock	X			
Gyro erect	X			

LIGHTING	No EMI Affect	EMI Affected Gnd	EMI Affected Flt	Explanation
Cockpit utility	X			
Cockpit flood	X			
Cabin dome	X			
Search light	X			
Search light control	X			
Landing light	X			
Flt instr lights (PLT)	X			
Flt instr lights (COPLT)	X			
Nonflight instr lights	X			
Console lights, upper	X			
Console lights, lower	X			
Position lights	X			
Formation lights	X			
Anticollision lights	X			
NVG lighting	X			

3.2.5 Battery life evaluation

Battery Life Evaluation
Report Form

Nomenclature: Blood pressure monitor
Manufacturer: Physio Control
Model number: LIFESTAT® 100
Serial number: 00003780
Military item number: None

Options installed: None

Manufacturer battery life specification: Approximately 2 hours in 5-minute cycle mode when fully charged.

Specified battery recharge time: 16 hours to fully charge depleted battery; 2 hours to provide 70 percent of full-charge capacity.

Specified mode of operation under battery power: 5-minute cycle mode, in which automatic blood pressure measurements are taken at 5-minute intervals.

Overall performance: Pass

Measurements: The unit averaged 5.5 hours of operation.

Comments: The unit was operated continuously in the 5-minute cycle mode until a low battery indication occurred. The depletion time was noted and the battery was recharged. This procedure was repeated three times.

3.2.6 Electrical safety test

Electrical Safety Test
Report Form

Nomenclature: Blood pressure monitor
Manufacturer: Physio Control
Model number: LIFESTAT® 100
Serial number: 00003780
Military item number: None
Line cord identification: Type SJT, 16/3 conductor, E53042 LL30875 (ICC colors)
Options installed: None

Date of test: 27 Oct 88

Measurements:

Grounding conductor resistance (milliohms): 78.7

Leakage current - Case to ground (microamperes):

unit off, grounded, normal polarity	1.9
unit off, ungrounded, normal polarity	10.3
unit off, ungrounded, reverse polarity	9.1
unit on, grounded, normal polarity	27.0
unit on, ungrounded, normal polarity	10.3
unit on, ungrounded, reverse polarity	9.2

MAXIMUM LIMITS:

ground resistance (milliohms):	150
current (microamperes)	
current (grounded, type A unit):	10
current (ungrounded, type A unit):	100
current (grounded, type B unit):	50
current (ungrounded, type B unit):	500

Comments on item setup or checks: None.

Comments on test run (including interruptions): Unit turned on, current measurements taken while pump was running.

Comments on other data: None.

3.2.7 Human factors evaluation

Human Factors Evaluation
Report Form

Nomenclature: Blood pressure monitor
Manufacturer: Physio Control
Model number: LIFESTAT® 100
Serial number: 00003780
Military item number: None

Options installed: None

Date of test: 27 Oct 88

Item configuration during test: Item prepared for operation, sitting on a counter top.

Checklist for HFE

RESULTS

VISUAL DISPLAYS: Satisfactory

- display type, format, content
- location of displays
- indicator lights
- scalar displays
- color coding
- legends and labels
- cathode ray tubes
- counters
- flags, go-no-go, center-null indicators

Comments: None

CONTROLS: Satisfactory

- location
- characteristics of controls
- labeling
- control - display relationships

Comments: None

TIME REQUIRED TO PREPARE FOR OPERATION (list in comment)

Comment: Less than 3 minutes

MAINTAINABILITY: Satisfactory

component location
component characteristics
rests and stands
covers, cases, access doors
handles
lubrication
component mounting
cord storage provisions
external accessibility
internal accessibility
list special tools required
list realistic inspection requirements
list realistic inspection intervals

Comments: No external calibration adjustments.

CONDUCTORS: Satisfactory

binding and securing
length
protection
routing
conductor coding
fabrication
connectors

Comments: None.

FASTENERS: Satisfactory

access through inspection panel covers
enclosure fasteners
device mounting bolts and fasteners

Comments: None.

TEST POINTS: n/a

general
location and mounting
test point labeling and coding

Comments: None.

TEST EQUIPMENT: Satisfactory

general
equipment self-test
indicators (list in comments)
controls
positive indication of proper operation

Comments: Test "T" connector not provided with unit.

FUSES AND CIRCUIT BREAKERS: Satisfactory

external accessibility
easy replacement or reset by operator

Comments: No fuses are externally accessible.

LABELS AND CODING: Satisfactory

placed above controls and displays
near or on the items they identify
not obscured by other equipment components
describe the function of the items they identify
readable from normal operating distance
conspicuous placards adjacent to hazardous items

Comments: None.

SAFETY: Satisfactory

manual
materials
fire and explosive protection
operator protection from mechanical hazards
patient protection from mechanical hazards
electrical safety (operator and patient)

Comments: None.

3.2.8 Altitude test

Altitude Test
Report Form

Nomenclature: Blood pressure monitor
Manufacturer: Physio Control
Model number: LIFESTAT® 100
Serial number: 00003780
Military item number: None

Options installed: None

Date of test: 24 Oct 88

Item configuration during test: Item turned on in the standby mode, sitting on chamber floor.

Performance test criteria: Consistent and accurate displays and measurements

Ambient conditions outside chamber:

Temperature	73°F
Humidity	67% RH
Barometric pressure	1 atm

PRETEST DATA

Pretest performance check:
Item functional (based on performance test criteria): Yes

Installation of item in test facility:

list connections to power	None (battery)
list connections to simulators	None
list connections to dummy loads	None
list unconnected terminals	Serial port

IN-TEST DATA

Time of test start: 1319

POSTTEST DATA

Posttest performance check (complete check of item and accessories):

Time of test end: 1445

Item functional (based on performance test criteria): Yes

Deviation from pretest: None

Comments on item setup or checks: None

Comments on test run (including interruptions): None

Comments on other data: None

3.2.9 Vibration test

Vibration Test
Report Form

Nomenclature: Blood pressure monitor
Manufacturer: Physio Control
Model number: LIFESTAT® 100
Serial number: 00003780
Military item number: None

Options installed: None

Date of test: 24 Oct 88

Item configuration during test: Item strapped down on vibration table fixture; ac and dc operation.

Performance test criteria: Consistent and accurate measurements and displays.

PRETEST DATA

Pretest performance check:
Item functional (based on performance test criteria): Yes

Installation of item in test facility:

list connections to power	120 Vac
list connections to simulators	None
list connections to dummy loads	Test engineer's arm
list unconnected terminals	None

Ambient conditions

Temperature	72°F
Humidity	66% RH
Barometric pressure	1 atm

IN-TEST DATA

Data and performance checks during test:

Time at first check:
X: 0835 Y: 0945 Z: 0840

Item functional (based on performance test criteria): Yes

Deviation from pretest: None

Time at second check:
X: 0930 Y: 1045 Z: 0930

Item functional (based on performance test criteria): Yes

Deviation from pretest: None

POSTTEST DATA

Posttest performance check (complete check of item and accessories):

Item functional (based on performance test criteria): Yes

Item intact: Yes

Deviation from pretest: None

Comments on item setup or checks: None

Comments on test run (including interruptions): None

Comments on other data: None

3.2.10 High temperature test

High Temperature Test
(Equipment Operating)
Report Form

Nomenclature: Blood pressure monitor
Manufacturer: Physio Control
Model number: LIFESTAT® 100
Serial number: 00003780
Military item number: None

Options installed: None

Date of test: 23 Nov 88

Item configuration during test: Unit was sitting on chamber floor, ready for operation.

Performance test criteria: Consistent and accurate displays and measurements.

Ambient conditions outside chamber:

Temperature	20.5°C
Humidity	57% RH
Barometric pressure	1 atm

PRETEST DATA

Pretest performance check:
Item functional (based on performance test criteria): Yes

Installation of item in test facility:

list connections to power	120 Vac
list connections to simulators	None
list connections to dummy loads	Test engineer's arm
list unconnected terminals	None
distance from north wall (meters)	0.75
distance from south wall (meters)	0.75
distance from east wall (meters)	2.0
distance from west wall (meters)	2.0
distance from ceiling (meters)	2.6
distance from floor (meters)	0.0

IN-TEST DATA

Time of test start: 0800

Performance checks during test:

First check:

Time:	0830
Temperature:	49°C
Humidity:	15% RH
Barometric pressure:	1 atm
Item functional (based on performance test criteria):	Yes, all ok
Deviation from pretest:	None

Second check:

Time:	0900
Temperature:	49°C
Humidity:	15% RH
Barometric pressure:	1 atm
Item functional (based on performance test criteria):	Yes, all ok
Deviation from pretest:	None

Third check:

Time:	0930
Temperature:	49°C
Humidity:	15% RH
Barometric pressure:	1 atm
Item functional (based on performance test criteria):	Yes, all ok
Deviation from pretest:	None

POSTTEST DATA

Posttest performance check:
(complete check of item and accessories)

Time of test end:	1400
Item functional (based on performance test criteria):	Yes, all ok
Deviation from pretest:	None

Comments on item setup or checks: None

Comments on test run (including interruptions): None

Comments on other data: None

3.2.11 High temperature storage test

High Temperature Test
(Equipment in Storage)
Report Form

Nomenclature: Blood pressure monitor
Manufacturer: Physio Control
Model number: LIFESTAT® 100
Serial number: 00003780
Military item number: None

Options installed: None

Date of test: 28 Nov 88

Item configuration during test: Sitting on chamber floor, in storage, not operating.

Performance test criteria: Consistent and accurate displays and measurements.

Ambient conditions outside chamber:

Temperature	23°C
Humidity	40% RH
Barometric pressure	1 atm

PRETEST DATA

Pretest performance check:

Item functional (based on performance test criteria): Yes

Installation of item in test facility:

list connections to power	None
list connections to simulators	None
list connections to dummy loads	None
list unconnected terminals	All
distance from north wall (meters)	0.75
distance from south wall (meters)	0.75
distance from east wall (meters)	2.0
distance from west wall (meters)	2.0
distance from ceiling (meters)	2.6
distance from floor (meters)	0.0

Time of test start: 1100

POSTTEST DATA

Posttest performance check:
(complete check of item and accessories)

Time of test end: 1730
Item functional (based on performance test criteria): Yes
Deviation from pretest: None

Comments on item setup or checks: None

Comments on test run (including interruptions): None

Comments on other data: None

3.2.12 Low temperature test

Low Temperature Test
(Equipment Operating)
Report Form

Nomenclature: Blood pressure monitor
Manufacturer: Physio Control
Model number: LIFESTAT® 100
Serial number: 00003780
Military item number: None

Options installed: None

Date of test: 25 Nov 88

Item configuration during test: Sitting on chamber floor, ready for operation.

Performance test criteria: Consistent and accurate displays and measurements.

Ambient conditions outside chamber:

Temperature	20°C
Humidity	55% RH
Barometric pressure	1 atm

PRETEST DATA

Pretest performance check:
Item functional (based on performance test criteria): Yes
All OK Pass

Installation of item in test facility:

list connections to power	120 Vac
list connections to simulators	None
list connections to dummy loads	Test engineer's arm
list unconnected terminals	None
distance from north wall (meters)	0.75
distance from south wall (meters)	0.75
distance from east wall (meters)	2.0
distance from west wall (meters)	2.0
distance from ceiling (meters)	2.0
distance from floor (meters)	0.0

Time of test start: 0750

Performance checks during test:

First check:

Time:	0820
Temperature:	0°C
Humidity:	n/a
Barometric pressure:	1 atm
Item functional (based on performance test criteria):	Yes
Deviation from pretest:	None

Second check:

Time:	0850
Temperature:	0°C
Humidity:	n/a
Barometric pressure:	1 atm
Item functional (based on performance test criteria):	Yes
Deviation from pretest:	None

Third check:

Time:	0920
Temperature:	0°C
Humidity:	n/a
Barometric pressure:	1 atm
Item functional (based on performance test criteria):	Yes
Deviation from pretest:	None

POSTTEST DATA

Posttest performance check:
(complete check of item and accessories)

Time of test end:	1000
Item functional (based on performance test criteria):	Yes
Deviation from pretest:	None

Comments on item setup or checks: None

Comments on test run (including interruptions): None

Comments on other data: None

3.2.13 Low temperature storage test

Low Temperature Test
(Equipment in Storage)
Report Form

Nomenclature: Blood pressure monitor
Manufacturer: Physio Control
Model number: LIFESTAT® 100
Serial number: 00003780
Military item number: None

Options installed: None

Date of test: 30 Nov 88

Item configuration during test: ac power cord and cuff tube coiled and laying on top of the unit. The unit is in storage, not operating.

Performance test criteria: Consistent and accurate displays and measurements

Ambient conditions outside chamber:

Temperature	21°C
Humidity	46% RH
Barometric pressure	1 atm

PRETEST DATA

Pretest performance check:

Item functional (based on performance test criteria): Yes

Installation of item in test facility:

list connections to power	None
list connections to simulators	None
list connections to dummy loads	None
list unconnected terminals	All
distance from north wall (meters)	0.75
distance from south wall (meters)	0.75
distance from east wall (meters)	2.0
distance from west wall (meters)	2.0
distance from ceiling (meters)	2.6
distance from floor (meters)	0.0

Time of test start: 0800

POSTTEST DATA

Posttest performance check:
(complete check of item and accessories)

Time of test end: 1430
Item functional (based on performance test criteria): Yes
Deviation from pretest: None

Comments on item setup or checks: None

Comments on test run (including interruptions): None

Comments on other data: The unit was allowed to return to ambient conditions overnight before final performance check.

3.2.14 Humidity test

Humidity Test
Report Form

Nomenclature: Blood pressure monitor
Manufacturer: Physio Control
Model number: LIFESTAT® 100
Serial number: 00003780
Military item number: None

Options installed: None

Date of test: 2 Dec 88

Item configuration during test: The unit was sitting on the chamber floor, ready for operation.

Performance test criteria: Consistent and accurate displays and measurements.

Ambient conditions outside chamber:

Temperature	19°C
Humidity	43% RH
Barometric pressure	1 atm

PRETEST DATA

Pretest performance check:
Item functional (based on performance test criteria): Yes

Installation of item in test facility:

list connections to power	120 Vac
list connections to simulators	Test engineer's arm
list connections to dummy loads	None
list unconnected terminals	None
distance from north wall (meters)	0.75
distance from south wall (meters)	0.75
distance from east wall (meters)	2.0
distance from west wall (meters)	2.0
distance from ceiling (meters)	2.6
distance from floor (meters)	0.0

IN-TEST DATA

Time of test start: 1000

Performance checks during test:

First check:

Time:	1045
Temperature:	30°C
Humidity:	94% RH
Barometric pressure:	1 atm
Item functional (based on performance test criteria):	Yes
Deviation from pretest:	None

Second check:

Time:	1215
Temperature:	30°C
Humidity:	95% RH
Barometric pressure:	1 atm
Item functional (based on performance test criteria):	Yes
Deviation from pretest:	None

Third check:

Time:	1215
Temperature:	30°C
Humidity:	95% RH
Barometric pressure:	1 atm
Item functional (based on performance test criteria):	Yes
Deviation from pretest:	None

Fourth check:

Time:	1310
Temperature:	29.5°C
Humidity:	95% RH
Barometric pressure:	1 atm
Item functional (based on performance test criteria):	Yes
Deviation from pretest:	None

Fifth check:

Time:	1345
Temperature:	30°C
Humidity:	95% RH
Barometric pressure:	1 atm
Item functional (based on performance test criteria):	Yes
Deviation from pretest:	None

POSTTEST DATA

Posttest performance check:
(complete check of item and accessories)
Time of test end: 1515
Item functional (based on performance test criteria): Yes
Deviation from pretest: None

Comments on item setup or checks: None

Comments on test run (including interruptions): None

Comments on other data: None

3.2.15 Electromagnetic characteristics test

****

Electromagnetic Characteristics Testing
Evaluation of Performance
****

T & E Item Number: 04 Date: 1 Nov 88

Nomenclature: Blood pressure monitor
Manufacturer: Physio Control
Model number: LIFESTAT® 100
Serial number: 00003780
Military item number: n/a

****

Conducted emissions tests

CE01
Testing configuration(s): n/a
Performance (pass/fail): n/a

Comments: n/a

CE02
Testing configuration(s): Operating on copper work bench.
Performance (pass/fail): Pass

Comments: Both hot and neutral conductors tested.

CE04
Testing configuration(s): Operating on copper work bench.
Performance (pass/fail): Fail

Comments: NB failure 0.4 to 13.5 dB over specifications in range 1.7 to 41.7 MHz; BB failure 0.5 to 12.9 dB over specifications in range 1.8 to 26.7 MHz.

Conducted susceptibility tests

CS02
Testing configuration(s): Operating on test bench, connected to test jig.
Performance (pass/fail): n/a

Comments: Unable to test because noise generated by the unit is greater than the test signal (unable to measure test signal).

CS06 Testing configuration(s): Operating on counter top.
Performance (pass/fail): Pass

Comments: None

Radiated emissions tests

RE02 Testing configuration(s): Operating on wooden test stand in the EMC chamber, ac and battery power.
Performance (pass/fail): Fail

Comments: NB failures 0.2 to 45.7 dB over specifications in range 0.5 to 317 MHz; BB failures of 0.4 to 33.7 dB over specification in range 10 to 100 MHz.

Radiated susceptibility tests

RS03 Testing configuration(s): Operating on the wooden test stand in the EMC chamber, ac power only.
Performance (pass/fail): Pass

Comments: Susceptible to 4.22 V/m vertical polarity, and 10 V/m horizontal polarity, both at 30 MHz. All segments of LED illuminated at once.

3.3 CRITERIA, SIGNIFICANT PROBLEMS, AND SUGGESTED IMPROVEMENTS

3.3.1 Criteria

Item No.	Criteria (Source)	Remarks	Applicable subparagraph
1	The physical inventory is conducted solely for investigation and documentation.	n/a	2.1.2.1
2	The LIFESTAT® 100 will display consistent and accurate measurements.	met	2.1.2.2
3	Verify manufacturer's specified full power internal battery life expectancy of 2 hours during continuous operaton in the 5-minute cycle.	met	2.2.2
4	The LIFESTAT® 100 will meet the limits established in NAFP 99 for electrical safety of medical equipment.	met	2.3.2
5	The LIFESTAT® 100 will be rated satisfactory in all major categories of the evaluation. These include: Visual displays, controls, maintainability, conductors, fasteners, test points, test equipment, fuses and circuit breakers, labels and coding, and safety.	partially met	2.4.2
6	The LIFESTAT® 100 will display consistent and accurate measurements while exposed to an altitude equivalency of 15,000 feet above sea level.	met	2.5.2
7	The LIFESTAT® 100 will remain operational and display consistent and accurate measurements while exposed to vibrational stresses.	met	2.6.2

8	The LIFESTAT® 100 will display consistent and accurate measurements during the high temperature operation check.	met	2.7.2.1
9	The LIFESTAT® 100 will display consistent and accurate measurements after the high temperature storage.	met	2.7.2.2
10	The LIFESTAT® 100 will display consistent and accurate measurements during the low temperature operation check.	met	2.8.2.1
11	The LIFESTAT® 100 will display consistent and accurate measurements after the low temperature storage.	met	2.8.2.2
12	The LIFESTAT® 100 will display consistent and accurate measurements while exposed to a high humidity.	met	2.9.2
13	The LIFESTAT® 100 will not produce emissions in excess of the limits set forth in MIL-STD-461A, Notice 4, paragraph 6.13.	partially met	2.10.2.1
14	The LIFESTAT® 100 will not malfunction when it is subjected to radiated fields as specified in MIL-STD-461A, Notice 4, paragraph 6.20.	met	2.10.2.2
15	The LIFESTAT® 100 will not conduct emissions in excess of the limits set forth in paragraphs 6.1 and 6.2, MIL-STD-461A, Notice 4.	partially met	2.10.2.3
16	The LIFESTAT® 100 will not malfunction when it is subjected to conducted emissions as specified in MIL-STD-461A, Notice 4, paragraphs 6.7 and 6.10.	partially met	2.10.2.4

17	The flight surgeon will be able to operate the LIFESTAT® 100 without physical or functional restrictions aboard the aircraft.	partially met	2.11.2.1
18	The LIFESTAT® 100 will not radiate EMI to disrupt or interfere with the other equipment or systems aboard the aircraft.	met	2.12.2.2
19	The aircraft will not radiate EMI to disrupt or interfere with the LIFESTAT® 100.	met	2.12.2.3

3.3.2 Significant problems which require corrective action

None

3.3.3 Suggested improvements

None

3.4 REFERENCES

3.4.1 Department of Defense. 1971. EMI characteristics, requirements for equipment. Washington, D.C. MIL-STD-461A, Notice 4. February.

3.4.2 Department of Defense. 1971. EMI characteristics, measurement of. Washington, D.C. MIL-STD-462, Notice 3. February.

3.4.3 Department of Defense. 1983. Environmental test methods and engineering guidelines. Washington, D.C. MIL-STD-810D. July.

3.4.4 Department of Defense. 1989. Human engineering design criteria for military systems, equipment, and facilities. Washington, D.C. MIL-STD-1472D. March.

3.4.5 Department of the Army. 1987. Maintenance management procedures for medical equipment. Washington, D.C. TB 38-750-2. April.

3.4.6 Department of Army. 1982. Environmental protection and enhancement. Washington, D.C. AR 200-1. June.

3.4.7 Underwriters Laboratory's, Inc. 1978. Standard for safety, medical and dental equipment. Chicago, Illinois. UL-544.

3.4.8 Department of Defense. 1989. Human engineering design criteria for military systems, equipment, and facilities. Washington, D.C. MIL-STD-1472D. March.

3.4.9 Association for the Advancement of Medical Instruments. Human factors engineering guidelines and preferred practices for the design of medical devices. Arlington, Virginia. AAMI-HE-1988. February.

3.4.10 Department of the Army. 1978. Operator's manual, UH-60 and EH-60 helicopter, with changes 1-5. Washington, D.C. TM 55-1520-237-10. January.

3.4.11 Department of the Army. 1987. Maintenance management procedures for medical equipment. Washington, D.C. TB 38-750-2. April.

3.4.12 National Fire Protection Association. 1987. Standard for health care facilities. Quincy, Massachusetts. NAFP 99. February.

3.4.13 Physio Control. 1985. Operating instructions, LIFESTAT® 100 noninvasive blood pressure monitor. Redmond, Washington. P/N 802609-01.

3.5 ABBREVIATIONS

ac	alternating current
AVSCOM	U.S. Army Aviation Systems Command
AEST	aeromedical equipment suitability test
AWR	airworthiness release
BB	broadband
BPM	beats per minute
CAAF	Cairns Army Airfield
CRT	cathode ray tube
dB	decibel
dc	direct current
ECG	electrocardiograph
EMC	electromagnetic compatibility
EMI	electromagnetic interference
fpm	feet per minute
GFE	government furnished equipment
Gpk	gravity, peak
G(rms)	gravity (root mean square)
Hz	hertz
IAW	in accordance with
ITOP	in-flight test operating procedure
IGE	in-ground effect
kHz	kilohertz
KIAS	knots indicated airspeed
LCD	liquid crystal display
LED	light emitting diode
LIFESTAT® 100	Physio Control blood pressure monitor, model LIFESTAT® 100
LISN	line impedance stabilization networks
MEDEVAC	medical evacuation
MHz	mega hertz
MIL-STD	military standard
mL	milliliter
mm	millimeter
mmHg	millimeters of Mercury
m.s.l.	mean sea level
NAFP	National Association of Fire Prevention
NB	narrowband

NBC	nuclear, biological, and chemical
NiCad	nickel cadmium
NVG	night vision goggle
RAM	random access memory
RF	radio frequency
RH	relative humidity
ROM	read only memory
TB	technical bulletin
TFT	technical feasibility testing
T & E	test and evaluation
UES	Universal Energy Systems, Inc.
USAARL	U.S. Army Aeromedical Research Laboratory
V/m	volts per meter

3.6 LIST OF MANUFACTURERS

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3.6.3 Neurodyne-Dempsey, Inc.
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3.6.4 Tenney Engineering, Inc.
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3.6.5 Unholtz-Dickey Corporation
6 Brookside Drive
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3.6.6 Solar Electronics Company
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3.6.7 Tektronix, Inc.
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